

25, 1998, issued March 7, 2000 as U.S. Patent No. 6,033,390.—

Page 6, between paragraphs 3 and 4 insert the following: --

-- The invention is further, briefly, a pad for use with a continent ostomy port includes a body portion defining an aperture appropriately sized to place around the catheter of a continent ostomy port. The body portion of the pad is sized and shaped for placement against a user's skin beneath a face plate of the ostomy port. The pad is formed of a soft, flexible material to thereby cushion and protect a user's skin from contact with the ostomy port face plate, wherein the pad body portion has a distal surface which is domed and provided with a central indented region to thereby accommodate the distal portions of the continent ostomy port.--

Page 9, between paragraph 3 and 4, insert the following paragraphs: --

Fig. 28 is a schematic top plan view of a moisture barrier shim constructed in accordance with the invention.

Fig. 29 is a sectional view taken on line 29 – 29 of Fig. 28.

Fig. 30 is a sectional view taken on line 30 – 30 of Fig. 28.

Fig. 31 is a schematic upper perspective view of another embodiment of a moisture barrier/pad constructed in accordance with the present invention.

Fig. 32 is the same view as Fig. 31, but with a COP shown in place, to illustrate use of the pad.

Fig. 33 is a side elevational view of the pad of Fig. 31.

Fig. 34 is a bottom perspective view of the pad of Fig. 31.

Fig. 35 is a top plan view of the pad of Fig. 31.--

Page 30, before the first full paragraph, insert:--

With reference to Figs. 28 through 35, there is disclosed another embodiment of the moisture barrier previously discussed herein with reference to Fig. 4. Figs. 28 – 30 illustrate a “shim”, generally designated 157, which is optionally used with a moisture barrier/pad 158 described hereafter . Shim 157 is substantially flat and in the preferred embodiment shown has a generally oval-shaped perimeter 157a, as illustrated in Fig. 28. Perimeter 157a is shaped to match the perimeter of pad 158. Thus, if the shape of the pad is something other than oval, if desired, the exterior perimeter of shim 157 can be altered accordingly. The overall size of shim 157 can vary, as desired, to either match the size of moisture barrier/pad 158, so as to act as a riser for the COP face plate, or the shim may be sufficiently smaller in exterior dimension to permit it to be seated within the underside (proximally) of COP 200 for enhanced absorption of stomal fluids.

The sectional views shown in Figs. 29 and 30 illustrate an example of useful dimensions (in inches) for shim 157, but it is foreseen that other dimensions will suffice, depending upon the particular circumstances of use, including stoma size and COP dimensions.

Shim 157 has a preferably circular interior side wall, which defines a through-hole 157b to surround the stoma. The size and shape of the throughhole can be varied as may be necessary to accommodate any variations in size and shape stomas of various individual users. The arrow indicated by “X” in Fig. 29 illustrates one useful surface site on shim 157 for optional

application of an adhesive, such as a pressure sensitive adhesive and/or web adhesive, for example.

Figs. 31 – 35 illustrate an alternative embodiment, generally designated 158, of the new moisture barrier /pad. Inconsistencies in size between the figures may exist due to copying anomalies. In the preferred version shown, pad 158 is formed of molded foam material and has a low profile, as seen if Fig. 33, with a generally oval perimeter 158a (Fig. 35), although other perimeter designs can be useful. The pad body 159 has an outer (distal) surface 159a that is slightly domed, but formed in the central portion thereof with an indented region that accommodates the distal portions of a COP, such as that generally designated as 200 in Fig. 32. In this embodiment, upper surface 159a is formed with a central depressed area that is generally cross-shaped, extends down into the body 159 and has a substantially flat floor 163. Floor 163 defines a central aperture 160 with a side wall 161, which is shown circular, but can be other shapes, if desired, to accommodate the shape of a catheter, such as that indicated at 214 in Fig. 32.

Floor 163 of pad 158 extends away from aperture 160 in two opposed channels 165, each having opposed, angled side walls 167, as seen most clearly in Figs. 31, 32 and 33. Channels 165 offer easy finger access to an optional grip 242 on a cap 228 of a COP.

Floor 163 extends at approximate right angles to channels 165 from aperture 160 in two opposed cut-out areas 169 bounded by arcuate walls 171 disposed radially outwardly from the center of pad 158. Floor 163 between cut-out areas 169 may be in the same plane as floor 163

between channels 165, if desired, or slightly stepped down, as is preferred and as is shown in Fig. 31. Cut-out areas 169 provide spaces in pad 158 to accommodate the COP 200 features, such as a bolster inflation port, as indicated at 252, or an access port for an ARV, as indicated at 254 in Fig. 32.

Fig. 34 shows that the lower (proximal) surface of pad 158 is preferably, although not necessarily, provided with a depending ring 158b. Ring 158b is disposed coaxially with opening 160, but spaced radially outward from opening 160 by a sufficient distance that ring 158b can be positioned outwardly of the stoma when pad 158 is in normal use position. Ring 158b preferably extends transverse to pad body 159, and slightly past the proximal extent of body 159, as illustrated in Fig. 33. Alternatively, ring 158b can be omitted altogether, or can be shorter than the depth of the perimeter of pad 158. When ring 158b is present, a preferably continuous channel 158c is formed between ring 158b and perimeter 158a of pad 158. Channel 158c is optionally sized and shaped to correspond to and to receive shim 157, so that shim 157 is disposed in normal use between the bottom of pad 158 and the user's skin. Shim 157 can also be nested in the underside of pad 158 without the presence of ring 158b. This arrangement is especially useful if the shim is to provide wicking properties. Alternatively, as previously discussed, the shim can have exterior dimensions which correspond to the exterior perimeter dimensions of pad 158, or which even extend slightly beyond the perimeter of the pad.--

Page 40, paragraph 1, please replace the Abstract with the following paragraph:

-- A pad for use with a continent ostomy port includes a body portion defining an